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Imagyn

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510(k) Summary

Submitted By: Imagyn Medical, Inc.
27651 La Paz Road
Laguna Niguel, CA 92677-3917
(714) 362-2500
Contact: Debra A. Rinderer

Summary Preparation: September 5, 1996

Device: Imagyn Falloposcopy System

Predicate Devices: Baxter Healthcare Corp. LE PTA Catheter
Conceptus Fallopian Tube Catheterization System
OvaMed GyneSys Dx Uterine Ostial Access Catheter
OvaMed Saratoga Modular Miniature Endoscope System
Optimed Technologies, Inc. Flexible Fiber Optic Hysteroscopes

Device Description: The Imagyn Falloposcopy System consists of the following components:

- Linear Everting (LE) Fallopian Tube Access Catheter
- Falloposcope

Intended Use of Device: The Imagyn Falloposcopy System is indicated for intratubal catheterization for evaluation of occlusions in the fallopian tube. ✓

Technological Comparisons: The device has equivalent technological characteristics to the predicate devices to achieve intratubal catheterization for evaluation of occlusions in the fallopian tube.

Performance Summary: Clinical and non-clinical tests were performed to demonstrate that the device performed according to its description and intended use.

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